Applicants: Jingrong Cao et al.
Application No.: 10/696,862

PRE-APPEAL BRIEF REQUEST FOR REVIEW

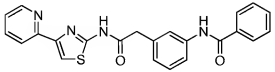
The rejection under 35 U.S.C. § 103(a)

In the April 16, 2008 Final Office Action (hereafter, "the Final Office Action"), the Examiner rejected claims 1, 4, 5, 8-12, 14-20, 23-29, 31, 33-46, and 54-57 under 35 U.S.C. § 103(a) for allegedly being obvious in view of Inaba et al., Japanese Patent Application No. 2002053566 (hereafter, "Inaba"). In particular, the Examiner asserted that the compounds of Inaba are kinase inhibitors useful for the treatment of Alzheimer's disease and allergy, and that some of the compounds of Inaba are positional isomers of the compounds of the present invention, therefore making the compounds of the present invention not patentably distinct. This action is improper because the Examiner has failed to identify that portion of Inaba that describes or demonstrates that the compounds therein are useful for the treatment of Alzheimer's disease or allergy. Furthermore, in his obviousness rejection the Examiner has failed to identify a reason that would have prompted a person of ordinary skill in the art to make the claimed invention.

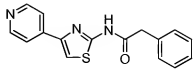
When establishing the differences between the prior art and the present invention in the obviousness rejection of the November 1, 2007 Office Action (hereafter, "the November Office Action"), the Examiner stated that Inaba describes compounds that are useful for the treatment of Alzheimer's disease or allergy. In responding to the November Office Action, applicants stated that they were unable to find the relevant descriptive text in Inaba that relates to the treatment of these diseases by the compounds described therein and provided a Chemical Abstracts Service abstract indicating that the compounds of Inaba were prepared as sedatives. At this time it was also pointed out to the Examiner that, according to the Manual of Patent Examining Procedure (MPEP) § 707.07, "[i]n citing foreign published applications or patents, in case only a part of the document is involved, the particular pages and sheets containing the parts relied upon will be identified."). See paragraph 2 on page 60 of the Reply to the November Office Action. In the Final Office Action, the Examiner provided a

Japanese-to-English machine translation of Inaba in its entirety, but still failed to point to that part of the document that he has relied on for his rejection. Instead, the Examiner cited sections of Inaba relating to the description of the compounds of the Inaba invention (i.e., the generic formula found on page 1 and the compound table found on pages 23-99). The pages of Inaba relating to the use of the compounds described therein for treating Alzheimer's disease or allergy were not identified by the Examiner at any juncture during the prosecution of the instant application. Further, applicants have been unable to find such a section in the translation of Inaba that was provided by the Examiner. See pages 54-55 of the Reply to the Final Office Action. Accordingly, the maintained obviousness rejection in the Final Office Action was improper because applicants were not given enough information to properly formulate a rebuttal to the Examiner's assertion that the uses of the compounds of Inaba relate to the uses of the compounds of the instant invention.

In the Final Office Action, the Examiner also asserted that the compounds of Inaba are closely related positional isomers of the compounds of the present invention and that it would have been obvious to one skilled in the art at the time the invention was made to expect the compounds of the present invention to possess the utility taught by the compounds of Inaba. The Examiner particularly pointed out compounds 51 and 80 (structures shown below) and stated that there was no proviso in claim 54 to exclude these compounds. Applicants respectfully traversed for the following reasons. First, pending claim 54 is dependent upon claim 1, which excludes compound 80. Second, there is no reason to exclude compound 51 since it is outside the scope of claim 1.

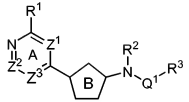


Inaba compound 51

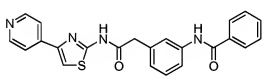


Inaba compound 80

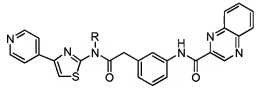
Most importantly, only 7 (2%) of the 306 compounds that are exemplified in Inaba have a pyridyl substituent at the position corresponding to the Ring A pyridin-4-yl substituent of the compounds of the present invention (see below for the structure of compounds of formula I). As was stated in the Reply to the November Office Action, biological data are presented for only 2 of these 7 compounds (compounds 44 and 113, see below for structures) and the data demonstrate that these two compounds are inferior enzyme inhibitors compared to the vast majority of the other compounds of Inaba for which similar data are reported. See page 62, paragraph 2 of the Reply to the November Office Action.



formula I



Inaba compound 44



Inaba compound 113 (R is H)

For example, of the 246 Inaba compounds for which PKC IC_{50} data are reported, 222 compounds (90%) have activity that is more potent than compound 44 against any one of the tested isoforms (PKC-α, PKC-βII, and PKC-γ). Moreover, the Manual of Patent Examination Procedure (MPEP) states that "[h]omology and isomerism involve close structural similarity which must be considered with all other relevant facts in determining the issue of obviousness" and that these factors "should not be automatically equated with *prima facie* obviousness because the claimed invention and the prior art must each be viewed 'as a whole.'" See MPEP § 2144.09 (II). See also MPEP § 2141.02, which states that "[a]scertaining the differences between the prior art and the claims at issue requires

interpreting the claim language, and considering both the invention and the prior art references as a whole" (emphasis added). The specific compounds of Inaba cited by the Examiner in his obviousness rejection represent a small sub-genus of the compounds described therein and are not reflective of the Inaba reference as a whole. Further, no biological activity was reported in Inaba for cited compounds 51 and 80. Further still, the only biological activity data by Inaba for pyridinyl thiazole compounds indicate that these compounds are inferior kinase inhibitors compared to the vast majority of the other compounds described therein, thus teaching away from the preparation or use of pyridinyl thiazoles as kinase inhibitors. Therefore, Inaba provides no reason for a person of ordinary skill in the art to prepare the compounds of the present invention.

Conclusion

As stated herein, the Examiner failed to indicate that portion of Inaba that relates the biological activity of the compounds described therein to the compounds of the present invention. Nor was any rationale identified that would have led a person of ordinary skill in the art to modify the compounds of Inaba to make the pyridin-4-yl compounds of the present invention. Therefore, applicants respectfully request that the Examiner withdraw the rejections of claims 1, 4, 5, 8-12, 14-20, 23-29, 31, 33-46, and 54-57 under 35 U.S.C. § 103(a).

Respectfully submitted,

/Daniel A. Pearson/

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